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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,877	05/18/2006	Thomas Dunker	DUNKER ET AL-2 PCT	3786

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EXAMINER	
MERENE, JAN CHRISTOP L	
ART UNIT	PAPER NUMBER
3733	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,877	DUNKER ET AL.	
	Examiner	Art Unit	
	JAN CHRISTOPHER MERENE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is the initial Office action based on the 10/579,877 application filed on May 18, 2006 which is a 371 of PCT/EP03/12888 filed on November 18, 2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 7, 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claims 3, 7, 11, the use "preferable" in claim 3 and "preferably" in claims 7, 11 renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

5. Claim 12 recites the limitation "centred venting boring" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. The examiner will treat the claim with art as best understood.

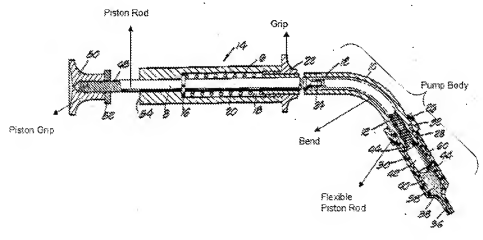
Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-7, 14** are rejected under 35 U.S.C. 102(b) as being anticipated by Shmitz US 3,724,076.

Regarding **Claim 1**, Shmitz discloses an injection pump (#14) for application of highly viscous media that have to be applied with pressure, in particular during percutaneous vertebroplasty, in which a piston system with grip ends to take up bone cement is provided in a piston, wherein a piston rod is rigidly arranged at a piston rod grip of the Injection pump and the distal end of the rigid piston rod is provided with a flexible piston rod to the distal end of a pump body with an end piston head, where the pump body is fastened at the proximal end at a grip of the Injection pump (as seen in Fig below).



Regarding **Claim 2**, Shmitz discloses the length of the rigid piston rod being dimensioned in such manner that the rigid piston rod remains in the pump body when the piston rod is pulled out through the grip by means with the piston rod grip (as seen in Figs 1-2, where the rigid piston rod remains in the pump body even when the piston rod is pulled out).

Regarding **Claim 3**, Shmitz wherein the pump body is flexible or ductile with preferable use of a plastic material for the pump body (see Col 1 lines 47-48, where the device can be made out of metal, a ductile material).

Regarding **Claim 4**, Shmitz discloses the body has a rigidly bent shape (as seen in the figure in claim 1).

Regarding **Claim 5**, Shmitz discloses the flexible piston rod is matched to the chose rigid deformation of the pump body (as seen in Figs above and see Col 2 lines 40-46).

Regarding **Claim 6**, Shmitz discloses the flexible piston rod is matched to the shape of the pre-formed pump body (as seen in Figs above and see Col 2 lines 40-46).

Regarding **Claim 7**, Shmitz discloses the flexible piston rod is fitted at its end with a relatively soft or flexible material, preferably a plastic material (see Col 1 line 64-67, where the piston at the end of the flexible rod is made out of plastic).

Regarding **Claim 14**, Shmitz discloses the pump body is arranged at the grip firmly, rotatable and replaceable (as seen in the fig in claim 1 above and see Col 2 lines 66-67 and Col 3 lines 1-5, where the body arranged at the grip is rotatable and replacable).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 in view of Fischione US 4,655,749.

Shmitz discloses a piston head (#42) is arranged in the pump body at the distal end of the flexible piston rod but does not specifically disclose sealing rings between piston head and pump body to create a suction effect when pulling out the piston rods in proximal direction.

However Fischione discloses a piston head with sealing rings (#56) which are used to create a suction effect (see Fig 3 and Col 3 lines 40-44, 60-68 and Col 4 lines 38-66, where rings are provided to seal the chamber and prevent leakage, creating a suction effect when the piston #36 is moved up and down).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection pump of Shmitz with the sealing rings (o rings #56) of Fisschione because they prevent leakage of fluid and sealing rings such as O-rings are well known in the art for creating a suction effect within an injection pump device (see Col 3 lines 60-68 and above).

12. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 and Fischione US 4,655,749 as applied to claim 8 above, and further in view of Baidwan et al US 5,238,003.

Shmitz and Fishione disclose the claimed invention as discussed above but does not specifically disclose the piston head at the flexible piston rod has a centred venting boring, with the rear section of the boring being equipped with an air-permeable filter, preferably of foam material or cellulose.

However, Baidwan discloses a similar device with a piston (#17) with a centered venting boring (#24) and an air permeable filter (#25 and see Col 4 lines 6-18).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection pump of Shmitz and Fishione to include the filter and venting boring of Baidwan because the filter and the venting boring allows air to pass but is impervious to fluids (See Col 4 lines 6-18).

13. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 and Fischione US 4,655,749 as applied to claim 8 above, and further in view of Kvitrud US 4,632,672.

Shmitz and Fishione disclose the claimed invention as discussed above but does not specifically disclose a centred venting boring in the piston head that is provided with a vertical boring, which vertical is radially covered with a valve hose.

However, Kvitrid discloses a similar device with a centred venting boring in a piston head with a vertical boring, where the vertical is radially covered with a valve hose (#26 and see Col 3 lines 18-51 and see Figs below).

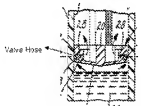


FIG. 2

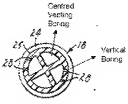


FIG. 4

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection pump of Shmitz and Fishione to include the

centred venting boring, vertical boring, and valve hose of Kvitrid because the borings are used to allow air to escape, where the valve hose selectively closes off the vertical boring to control air flow (see Col 3 lines 18-51).

14. **Claims 9, 10, 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 in view of Century US 5,513,630.

Shmitz discloses the claimed invention as discussed above, wherein the injection pump has a Luerlock (#36) for attachment with a nozzle (#30 and see Col 2 lines 54-61), but does not specifically disclose a hose bracket sleeve with an attached rotatable male LuerLock at the distal end of the pump body, wherein a nozzle is screwed to the rotatable male LuerLock to take up highly viscous media from a respective vessel which nozzle can be unscrewed after absorption of such highly viscous media, wherein the male LuerLock is fitted with a prong to fasten the pump body by radially pressure-forcing the pump body into place.

However, Century discloses disclose a hose bracket sleeve with an attached rotatable male LuerLock at the distal end of the pump body, wherein a nozzle is screwed to the rotatable male LuerLock to take up highly viscous media from a respective vessel which nozzle can be unscrewed after absorption of such highly viscous media, wherein the male LuerLock is fitted with a prong to fasten the pump body by radially pressure-forcing the pump body into place (see figs below and Col 10 lines 59-65, Col 11 lines 4-24, which teaches a standard male LuerLock to connect with a nozzle, where the LuerLock is attached to the body and is rotatable with prongs that

help keep the LuerLock in place, which also exerts force on the body).

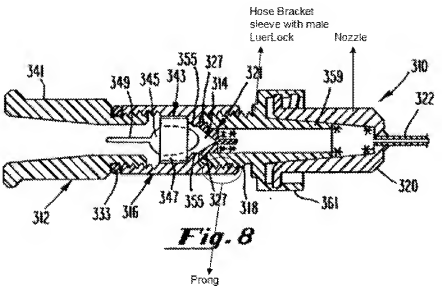


Fig. 8

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the LuerLock connection of the body with the nozzle of Shmitz et al with the rotatable male LuerLock connection and prongs of Century (as discussed in the previous paragraph) because it applies a known technique to a known device ready for improvement to yield predictable results of fastening a nozzle against an injection device, (see figs below and Col 10 lines 59-65, Col 11 lines 4-24). Furthermore, the rotatable male LuerLock with prongs fitted to a complimentary nozzle as taught by Century is also a simple substitution of known element for another to obtain predictable results of fastening a nozzle against an injection device.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3733
/Eduardo C. Robert/
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